



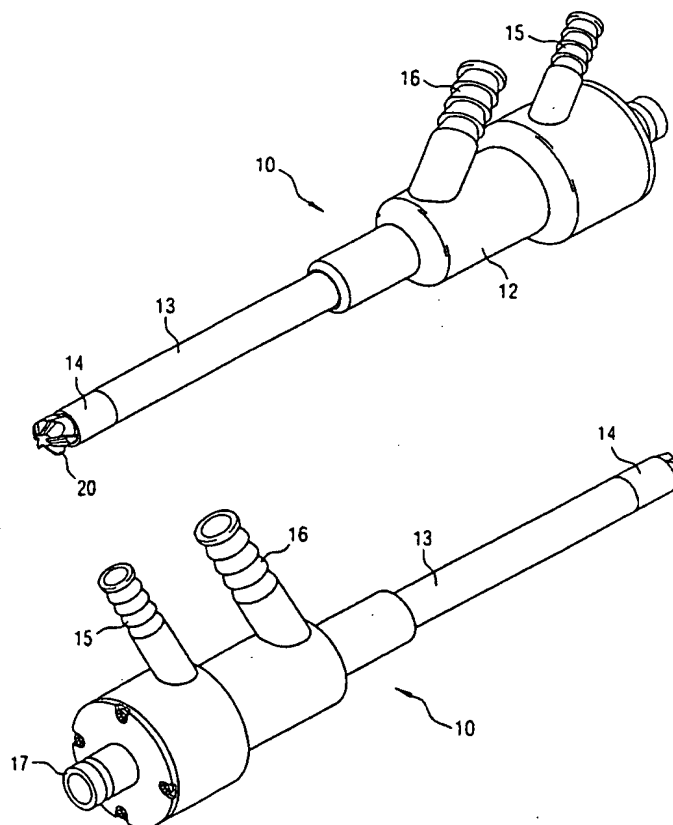
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61B 17/16		A1	(11) International Publication Number: WO 00/45714
			(43) International Publication Date: 10 August 2000 (10.08.00)
(21) International Application Number: PCT/CH00/00051		(81) Designated States: AU, CA, CN, JP, KR, NZ, US, ZA, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 1 February 2000 (01.02.00)		Published <i>With international search report.</i>	
(30) Priority Data: 60/118,485 3 February 1999 (03.02.99) US			
(71) Applicant (for all designated States except CA US): SYNTHES AG CHUR [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH).			
(71) Applicant (for CA only): SYNTHES (U.S.A.) [US/US]; 1690 Russel Road, P.O. Box 1766, Paoli, PA 19301-1222 (US).			
(72) Inventors; and (75) Inventors/Applicants (for US only): GREEN, James, M. [US/US]; 6720 S.W. Canyon Drive, Portland, OR 97225 (US). PERRIER, Alexandre, N. [CH/CH]; Dornacherstrasse 89, CH-4053 Basel (CH). KMIEC, Stanley, J., Jr. [US/US]; 663 W. Farmount Street, Coopersburg, PA 18036 (US).			
(74) Agent: LUSUARDI, Werther, Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).			

(54) Title: SURGICAL REAMER AND METHOD OF USING SAME

(57) Abstract

A device for expedited reaming of a medullary canal and method of using the same are disclosed. The device includes a reamer head (20; 20') connected at the distal end of a rotatable drive shaft (102). The reamer head (20; 20') has a cutting head (40) with a plurality of blades (41) and flutes therebetween. Each blade (41) has a front cutting portion. At least some of the blades have a front cutting portion that includes at least two and preferably at least three planar surfaces (51, 52, 53). The blades can also include a side cutting portion (44). The disclosed method for removing material from the medullary canal of a bone includes the steps of reaming an area of the medullary canal to remove material; irrigating the material to be removed while reaming to reduce generation of heat and move removed material from the reaming area; and aspirating the removed material while reaming to create a negative intramedullary canal pressure to assist in the removal of the material.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

SURGICAL REAMER AND METHOD OF USING SAME

The invention relates to a device for bone tissue removal, in particular for expedited reaming of a medullary canal as defined in the preamble of claim 1 and to a method for bone tissue removal, in particular for expedited reaming of a medullary canal as defined in the preamble of claim 16.

A wide variety of devices for cutting and removing bone tissue are known in the art. Examples of such include those described in U.S. Patent No. 5,269,785 issued to Bonutti, U.S. Patent No. 4,830,000 to Shutt, and U.S. Patent No. 5,190,548 to Davis. In general, these and similar devices utilize a rotating cutting tip similar to a drill displaced at the distal end of drive shaft. Bone cutting devices for use in reaming the medullary canal typically use a flexible drive shaft because the medullary canals of bones are seldom straight and usually will have some degree of curvature. Most reamers also have a central bore through both the reamer and the drive shaft. The central bore is intended to receive a long, small diameter guide pin or wire which is initially inserted into the medullary canal to act as a track for the advancing reamer.

Reamers are used in orthopedic surgery to prepare the medullary canals of bone for a wide variety of surgical procedures. Such procedures include total hip and knee replacement, nail insertion to stabilize a long bone fracture, an intramedullary osteotomy, and bone harvesting for grafting purposes.

From both a mechanical and a biological point of view, medullary reaming is particularly beneficial in improving the performance of implants. Specifically, reaming expands the medullary canal so that larger diameter implants can be inserted. These larger diameter implants are less likely to fail. In fact, certain fractures require over-reaming so that larger implants can be used. Without reaming, the surgeon must use a "best guess" estimate when selecting the diameter of the implant. The medical literature contains numerous case studies reporting the adverse consequences of an inaccurate estimate.

Reaming provides a direct measurement of the diameter of the medullary canal, and thereby allows for the selection of an implant that precisely fills the canal. As a

result, the stability of the fracture site is enhanced by achieving endosteal contact. When implants do not fill the medullary canal, load sharing between the implant and the bone is decreased. This increases the load that is transferred to the implant and promotes both implant failure and stress shielding of the bone.

Despite such benefits, negative consequences have also been associated with medullary reaming. In particular, current procedures for reaming the medullary cavity can result in an increase in both temperature and pressure. Like any process in which material is being removed, reaming causes generation of heat. Furthermore, a hydraulic pressure, which far exceeds that of blood pressure, builds up in the cavity during reaming. The reamer acts as a hydraulic piston within the bone cavity, and if the contents of the canal, which include a mixture of medullary fat, blood, blood clots, and bone debris, enter the blood stream, an embolism can result. Excessive heat has been associated with an increased incidence of aseptic necrosis of the cortex and elevated pressure has been associated with an increased risk of fat emboli. These complications are more likely to occur in patients when extenuating factors such as shock, existing lung contusion, multiple traumas, or pre-existing pulmonary impairment are present. In these situations, the preferred method of reaming would usually not be performed due to the increased risks involved.

Various devices and methods exist for reducing the intramedullary pressure build-up during reaming. For example, in prosthetic joint replacement, a distal venting hole, a large insertion hole, and a modified technique for cement insertion have all been shown to have some success in reducing pressure, and presumably, the chance of fat embolism. Venting holes in the bone only have little effect because their diameter is typically too small and local peak values must be assumed during the passage of the reamer. Similarly, reaming the medullary cavity less does not prevent pressure increase. In fact, pressure can be high even for reamers of small diameter.

Another technique which has been used in an attempt to reduce temperature and pressure is to perform the reaming in multiple steps with increasing size of reamers with each step. As a result, reaming procedures are done slowly with the application of gentle pressure and requiring multiple passes. Usually reaming is performed in 1 mm diameter increments until the bone cortex is reached and then in 0.5 mm

increments thereafter. In this regard, the reaming is carried out with less compression force and the intramedullary pressure can be easily reduced with most reaming devices utilizing this slow process. A faster reaming process utilizing fewer passes would be desirable in order to reduce operating time and medical costs.

Another disadvantage associated with current devices and methods is the reuse of reamers. Because current methods involve the use of multiple reamers of variable sizes to create one large opening in the medullary canal, reamers are usually reused in subsequent bone reaming procedures. As a result, reamers may become blunt over time and their continued use can produce greater intramedullary pressures and a greater increase in cortical temperature. Consequently, the careful attention of surgeons and operating staff to treat the reamers gently and replace them whenever necessary is trying and costly. A single use device is desirable to avoid the problems associated with the dulling of reamers which occurs with time.

Another disadvantage of current devices is due to the use of reamer designs with shallow flutes and large shafts. It has been shown that reamers with small shafts and deep flutes are more beneficial in reducing intramedullary pressure and temperature.

Thus, there exists a need for a device and method for reaming a medullary canal at an enhanced rate without increasing the risk of fat emboli and heat necrosis upon cutting and removal of bone tissue.

The invention solves this problem by means of a device for bone tissue removal, in particular for expedited reaming of a medullary canal and characterized by the features of claim 1, and furthermore by a method for bone tissue removal, in particular for expedited reaming of a medullary canal which is characterized by the features of claim 16.

The present invention relates to a device for reaming a medullary canal of a bone. The device includes a rotatable drive shaft connected at the proximal end to a rotational drive element and a reamer head rotatably coupled to the distal end of the drive shaft. The reamer head has a tubular shank engaging the distal end of the

drive shaft and a cutting head integral with the shank and having a plurality of blades. Flutes are located between adjacent blades. At least some and preferable all of the blades have a front cutting portion that includes at least two planar surfaces. A helical side cutting portion may be added to any or all of the blades. Preferably, there are at least five blades and each blade has at least three planar surfaces.

In one embodiment, each blade has a front cutting edge defined by the intersection between the inner blade wall and one of the planar surfaces. This front cutting edge may be oriented at an angle of approximately 30° to 45° with respect to the longitudinal axis of the tubular shank. In another embodiment, the helical side cutting portion further includes a side cutting edge defined by the intersection between the inner blade wall and the outer blade wall.

The drive shaft and reamer head each may have a cannulation. These two cannulations are aligned when the tubular shank is engaged with the drive shaft to form a center channel. One use for this channel is for receiving a guide wire that can be used to direct the device in the medullary canal.

The device may also include an aspiration tube for removing cut material generated by the reamer head. The aspiration tube has a manifold assembly at a proximal end, a reamer head retainer at a distal end, and a lumen configured and dimensioned to receive the drive shaft. Preferably, the center channel is in fluid communication with an irrigation source to provide irrigation to the cutting head. The manifold assembly may include an irrigation port connected to the irrigation source and an irrigation chamber in fluid communication with the irrigation port. The irrigation fluid travels from the irrigation chamber through an opening on the drive shaft and into the center channel. In one embodiment in which the reamer head is larger than the aspiration tube, the reamer head retainer has a substantially spherical outer profile.

The distal end of the lumen of the aspiration tube is in fluid communication with the flutes of the reamer head and the proximal end of the lumen is in fluid communication with a suction source. Preferably, the manifold assembly includes an aspiration port connected to the suction source to assist in the removal of the cut material.

The invention also relates to a method for removing tissue from a medullary canal of a bone. This method includes the steps of reaming an area of the medullary canal to remove the material; irrigating the material to be removed while reaming to reduce generation of heat and move removed material from the reaming area; and aspirating the removed material while reaming to create a negative intramedullary canal pressure to assist in the removal of the material.

The method may also include the step of inserting an implant in the medullary canal after the removal of material. Preferably, the reaming is done with a single reaming device, and the device may be guided to the appropriate location in the medullary canal using a guide wire which passes through a cannulation in the device. In another embodiment, the method includes the step of harvesting the removed tissue for use as a graft.

Preferred features of the present invention are disclosed in the accompanying drawings, wherein similar reference characters denote similar elements throughout the several views, and wherein:

FIG. 1A is a perspective view from the left side of one embodiment of a reamer device according to the present invention;

FIG. 1B is a perspective view from the right side of the device of FIG. 1A;

FIG. 2 is a top view of the reamer device of FIGS. 1A and 1B;

FIG. 3 is a cross-sectional view of the device taken along line A-A of FIG. 2;

FIG. 4 is a perspective view of one embodiment of a drive shaft assembly according to the present invention;

FIG. 5 is a side view of one embodiment of a reamer head according to the present invention;

FIG. 6 is a front view of the reamer head of FIG. 5;

FIG. 7 is a rear view of the reamer head of FIG. 5;

FIG. 8 is a front perspective view of the reamer head of FIG. 5;

FIG. 9 is a rear perspective view of the reamer head of FIG. 5;

FIG. 10 is an enlarged view of the side view of FIG. 5;

FIG. 11 is an enlarged and partially fragmented perspective and cross-sectional view of the reamer shown in FIGS. 1A and 1B;

FIG. 12 shows an exemplary sample of a graph expressing a pressure-time curve of a system using the reamer of FIG. 1, the reamer head of FIG. 5, and the drive shaft assembly of FIG. 4;

FIG. 13 is a perspective view of a portion of the drive shaft assembly of FIG. 4 with a guide wire inserted in the cannulation of the drive shaft;

FIG. 14 is a cross-sectional view of the drive shaft assembly taken along line A-A of FIG. 13;

FIG. 15 is a top view of another embodiment of a reamer device according to the present invention;

FIG. 16 is a front perspective view of another embodiment of a reamer head according to the present invention; and

FIG. 17 is an enlarged view of the side view of the reamer head of FIG. 16.

For convenience, the same or equivalent elements in the various embodiments of the invention illustrated in the drawings have been identified with the same reference numerals. Further, in the description that follows, any reference to either orientation or direction is intended primarily for the convenience of description and is not

intended in any way to limit the scope of the present invention thereto.

Referring to FIGS. 1-3, a first embodiment of a reamer 10 according to the present invention comprises a reamer head 20 located at a distal end of reamer 10 for reaming a medullary canal, a flexible aspiration tube 13 for suction and removal of the emulsified bone and other material generated by reamer head 20, a reamer head retainer 14 for retaining reamer head 20 on aspiration tube 13 while still allowing rotation of reamer head 20 with respect to aspiration tube 13, and a manifold assembly 12 at a proximal end of reamer 10. Thus, as used in this application, the term distal designates the end or direction near reamer head 20 and toward the front of reamer 10, and the term proximal designates the end or direction near manifold assembly 12 and toward the rear of reamer 10. The term longitudinal designates an axis central to aspiration tube 13.

Aspiration tube 13 is flexible so that it can bend to accommodate curvature of the bone and is preferably made of a translucent material so that the aspirated material can be observed. Manifold assembly 12 has an irrigation port 15 and an aspiration port 16 for connecting to an irrigation source and aspiration means respectively. A drive shaft coupling 17 is located at the proximal end of manifold assembly 12. Drive shaft coupling 17 can be readily attached and detached to a drive shaft or some other means for rotating reamer head 20.

FIG. 4 shows a drive shaft assembly 100 that can be used with reamer 10 to rotate reamer head 20 at sufficient speeds to ream the medullary canal. The use of a drive shaft assembly 100 with reamer 10 (or any modular system in which the driving means is contained in an unit that is independent from the reamer) allows drive shaft assembly 100 to be reused with many different reamers. Such modularity is advantageous because different patients and clinical conditions will require different sized reamer heads. Furthermore, the reamer head, and not the drive means, experiences the wear and abrasion of cutting bone. Thus, reamer 10 can be a single-use, disposable item and drive shaft assembly 100 can be used for an extended period.

Drive shaft assembly 100 includes a flexible drive shaft 102 having a reamer head

connector 104 on the distal end for releasably engaging reamer head 20 so that reamer head 20 rotates when flexible drive shaft 102 rotates, a power source connector 106 for connection to a source of power to initiate the rotation of drive shaft 102, and a manifold coupling 108 located between reamer head and power source connectors 104, 106 for engaging drive shaft coupling 17. Drive shaft 102 is sized to fit within the lumen of aspiration tube 13. However, as will be described in more detail later, there is sufficient space between the outer wall of drive shaft 102 and the inner wall of aspiration tube 13 to allow transport of aspirated material from reamer head 20 through aspiration tube 13 to aspiration port 16. As was the case for aspiration tube 13, drive shaft 102 is flexible to conform to any curvature of the bone being reamed. Drive shaft 102 has a cannulation 110 for accommodating a guide wire 120.

As seen best in FIGS. 11, 13, and 14, there is sufficient space between the outer wall of guide wire 120 and the inner wall of cannulation 110 to allow transport of an irrigation fluid from irrigation port 15 through cannulation 110 to reamer head 20. Drive shaft 102 has an opening 126 that extends from the outer surface of drive shaft 102 to cannulation 110. Opening 126 is positioned on drive shaft 102 so that when drive shaft assembly 100 is coupled to reamer device 10, opening 126 is in fluid communication with irrigation port 15 to allow irrigation to flow through cannulation 110. Opening 126 has curved walls 128, 130. Curved wall 128 bows out to have a convex profile and curved wall 130 curves inward to have a concave profile. The curvature of curved walls 128, 130 helps to draw water into cannulation 110 as drive shaft 102 rotates (which with respect to FIG. 14 is in the counter-clockwise direction).

Any suitable means for releasably joining manifold coupling 108 and drive shaft coupling 17 can be used. Preferably, a quick connect mechanism is used for rapid coupling and uncoupling. For example, manifold coupling 108 can have a spring loaded latch mechanism, such as ball bearings, which engage a slot in drive shaft coupling 17.

Similarly, any suitable power source and means for securing drive shaft assembly 100 to the power source can be used. As pneumatic tools are widely used in orthopaedic surgery, the power source is preferably an air drive such as the Compact

Air Drive available from Synthes (U.S.A.) of Paoli, Pennsylvania.

Referring back to FIG. 3, housed within manifold assembly 12 is a sealing element 34 and a sleeve bearing 31. Sealing means 34 and sleeve bearing 31 define an irrigation chamber 35 and provide a hermetic seal to prevent irrigation fluid from escaping irrigation chamber 35 into aspiration port 16 or out the proximal end of reamer device 10 during operation. In addition, sleeve bearing 31 prevents the aspirated emulsified material from entering irrigation chamber 35.

Reamer head 20 is positioned coaxially within reamer head retainer 14 at the distal end of aspiration tube 13. FIG. 15 shows a reamer 210 that has a reamer retainer 14' with a generally spherical outer profile shape. As head retainer 14' follows reamer head 20, the shape of head retainer 14' allows head retainer 14' to glance off of the medullary canal walls should flexing occur with aspiration tube 13 with respect to drive shaft 102. Thus, head retainer 14' can move smoothly while advancing through the medullary canal, retracting after reaming, and negotiating the fracture site.

Reamer head 20 is preferably made of a stainless steel, although any metallic, polymeric, ceramic, or composite material suitable for cutting bone can be used. A reamer cannulation 22 extends from the distal tip to the proximal end of reamer head 20 (FIGS. 7 and 8). Reamer cannulation 22 is aligned with cannulation 110 of drive shaft 102 so that a guide wire can extend from the proximal end of drive shaft 102 through the distal end of reamer head 20.

Although many different reamer heads can be used with reamer 10, 210, one embodiment is shown in FIGS. 5-10. As shown in these figures, reamer head 20 consists of a cutting head 40 integral with a tubular shank 25. The periphery of tubular shank 25 is cylindrical and has a retaining groove 26 indented around the periphery which accommodates an extension from the inside of reamer head retainer 14 and permits reamer head 20 to rotate while maintaining a fixed location longitudinally at the distal end of the aspiration tube 13. Tubular shank 25 has a drive shaft receptor 23 at the proximal end which is configured to accommodate reamer head connector 104 of drive shaft 102 so that reamer head 20 must rotate

when drive shaft 102 rotates. Although drive shaft receptor 22 can be of any shape conforming to the exterior profile of reamer head connector 104, it is preferably a female hex feature.

Cutting head 40 of reamer head 20 has a plurality of blades 41, preferably at least five in number, extending radially outwardly from reamer cannulation 22 to form a substantially helical pattern. Correlating the number of blades to the particular blade geometry and rotation speed is advantageous in order to allow for appropriate amount of bone material to be removed while providing efficient cutting. When too many blades are used with a given blade shape, the flutes become very shallow and less bone material can be removed as a result. When an insufficient number of blades is used, the reamer head is not efficient in cutting bone tissue. In fact, the reamer head may bind or jam while cutting bone matter.

Each blade 41 has a multiple surfaced angular distal end with a straight front cutting edge 42 joined to a helical side cutting edge 44. Front cutting edge 42 is defined by the intersection between an inner blade wall 45 and a planar first lip surface 51. The angle between inner blade wall 45 and first lip surface 51 is acute. A planar second lip surface 52 intersects first lip surface 51 at an obtuse angle to form a first lip edge 56. A planar third lip surface 53 intersects second lip surface 52 at an obtuse angle to form a trailing lip edge 58. Side cutting edge 44 is defined by the intersection between inner blade wall 45 and an outer blade surface 46 and is at a constant radial distance from the longitudinal axis and extends longitudinally in a helical fashion. Outer blade surface 46 whorls radially inward from side cutting edge 44 along an arc toward an inner blade wall of an adjacent blade. The space between such adjacent blades defines a flute 43 which, during operation, functions to funnel the cut medullary canal material towards the proximal end of reamer head 20 for removal from the bone cavity through aspiration tube 13 under vacuum. Inner blade wall 45 and outer blade surface 46 extend longitudinally on cutting head 40 terminating at the proximal end in a shoulder surface 48. Shoulder surface 48 abuts tubular shank 25.

FIGS. 16 and 17 show another embodiment of a reamer head 20' according to the present invention. Reamer head 20' does not have any side cutting edges, thereby substantially minimizing the risk of laterally reaming through the cortex of the bone.

Each blade 41 has a multiple surfaced angular distal end with a straight front cutting edge 42. Front cutting edge 42 is defined by the intersection between an inner blade wall 45 and a planar first lip surface 51. The angle between inner blade wall 45 and first lip surface 51 is acute. A planar second lip surface 52 intersects first lip surface 51 at an obtuse angle to form a first lip edge 56. Outer blade surface 46 whorls radially inward along an arc toward an inner blade wall of an adjacent blade. The space between such adjacent blades defines a flute 43 which, during operation, functions to funnel the cut medullary canal material towards the proximal end of the reamer head 20' for removal from the bone cavity through aspiration tube 13 under vacuum.

The use of reamer 10, which can be during open surgical, percutaneous, or any other minimally invasive procedure, will now be described referring primarily to FIG. 11. It should be noted that the use of reamer 210 is analogous to the use of reamer 10, the primary difference between reamer 10 and reamer 210 being the different geometries of head retainer 14 shown in FIG. 2 and head retainer 14' shown in FIG. 15. After the bone to be reamed has been accessed, guide wire 120 is inserted into medullary canal 122 of bone 124. The insertion of guide wire 120 is typically done using fluoroscopy to ensure proper placement of guide wire 120. Reamer 10, with an appropriate cutter (such as reamer head 20 or 20') attached and coupled with drive shaft 100, is then placed over guide wire 120 so that guide wire 120 passes completely through aspiration tube 13 and provides a track which reamer 10 follows as it reams canal 122. Preferably, reamer 10 coupled with drive shaft 100 has been connected to a driving means prior to insertion into medullary canal 122. Thus, guide wire 120 actually passes through cannulation 110 of drive shaft 102 and cannulation 22 of reamer head 20.

While reaming medullary canal 122, irrigation and aspiration are applied simultaneously. The irrigation substantially cools reamer head 20, medullary canal 122, and bone 124. A preferable irrigation source, which delivers the irrigation fluid at a sufficient rate and pressure, is a normal saline bag suspended one meter above irrigation port 15. It should also be noted that, in addition to a saline bag, any biological compatible solution and delivery system can be used as the irrigation source. The irrigation fluid passes from the irrigation source into irrigation port 15

and enters irrigation chamber 35. The irrigation fluid, traveling along the path indicated by arrows I, flows through cannulation 110 in the space between the inner wall of cannulation and guide wire 120 and out of reamer head 20.

The aspiration alleviates intramedullary pressure and helps to remove emulsified material from reamer head 20. The removal of material not only improves reaming, but also provides for the possibility of harvesting the emulsified material for grafting purposes. Suction created by an aspiration source travels along the path indicated by arrows A. Specifically, the irrigation fluid helps to channel the emulsified material generated by reamer head 20 through flutes 43 and into the space between the outer wall of drive shaft 102 and the inner wall of aspiration tube 13 to transport the emulsified material from reamer head 20 through head retainer 14, aspiration tube 13 and aspiration port 16 and into a suitable container.

A significant advantage of the system that includes reamer 10, 210, reamer head 20, and drive shaft assembly 100 is the ability to ream the medullary canal to the desired diameter in one pass, i.e. without the need to use multiple reaming heads of gradually increasing diameter until the desired reamed size is achieved. In this regard, supplying irrigation to reamer head 20 while simultaneously providing aspiration, and using a reamer head with efficient front cutting geometry (and optionally a side cutting geometry) produces less pressure and heat than prior art reaming devices.

FIG. 12 shows an exemplary sample of a graph expressing a pressure-time curve of the system according to the present invention in an animal model. Region I shows that no increase in pressure is induced when an access opening to the medullary canal is made. The increase in pressure in Region II results from standard techniques to gain access to the medullary canal. Region III shows that no increase in pressure is induced when the guide wire is inserted. As opposed to standard reaming process, the present invention reduces or eliminates intramedullary pressure. Specifically, the combined reaming, irrigating and aspirating functions to decrease intramedullary pressure below 0,1333 bar (100 mm Hg). In fact, as shown in Region IV, a negative intramedullary pressure is achieved with the system according to the present invention. Because the biologic threshold in the medullary

canal for fat emboli and pulmonary emboli is known to be greater than or equal to 0,2666 bar (200 mm Hg), the incidence of fat and pulmonary emboli is reduced. Additionally, heat necrosis of the cortex is also eliminated due to the cooling caused by the flow of fluid during the process.

FIG. 12 shows another important advantage of the system according to the present invention. Specifically, the medullary canal reaming (Region IV) requires approximately 50 seconds. In contrast, conventional reaming in the same animal model requires approximately 500 seconds. This decrease in reaming time by a factor of ten means that reaming in clinical situations can be reduced from 30 minutes to 3 minutes. Thus, operating times (and costs) can be significantly reduced without any increased risks.

While various descriptions of the present invention are described above, it should be understood that the various features can be used singly or in any combination thereof.

Therefore, this invention is not to be limited to only the specifically preferred embodiments depicted herein.

Further, it should be understood that variations and modifications within the scope of the invention may occur to those skilled in the art to which the invention pertains. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope of the present invention are to be included as further embodiments of the present invention. The scope of the present invention is accordingly defined as set forth in the appended claims.

CLAIMS

1. A device for reaming a medullary canal of a bone comprising:
 - A) a rotatable drive shaft (102) having proximal and distal ends and connected at a proximal end to a rotational drive element for causing rotation of the drive shaft (102); and
 - B) a reamer head (20;20') rotatably coupled to the distal end of the drive shaft (102), said reamer head (20;20') comprising:
 - C) a tubular shank (25) having a longitudinal axis and engaging the distal end of the drive shaft (102); and
 - D) a cutting head (40) integral with the shank (25) and having a plurality of blades (41) and flutes therebetween for cutting and reaming of bone, characterized in that
 - E) at least some of the blades (41) have a front cutting portion with at least two planar surfaces (51;52;53).
2. Device according to claim 1 wherein at least some of the blades (41) have a front cutting portion and a helical side cutting portion with the front cutting portion including at least two planar surfaces.
3. Device according to claim 1 or 2 wherein each blade (41) has inner and outer blade walls (45;46), a front cutting portion and a helical side cutting portion, with the front cutting portion further comprising a front cutting edge (42) defined by an intersection between the inner blade wall (45) and one of the planar surfaces (51;52;53).
4. Device according to claim 3 wherein the front cutting edge (42) is oriented at an angle from about 30° to about 45° with respect to the longitudinal axis of the tubular shank (25).
5. Device according to one of the claims 2 to 4 wherein the helical side cutting portion further comprises a side cutting edge (44) defined by an intersection between the inner blade wall (45) and the outer blade wall (46).

6. Device according to one of the claims 1 to 5 wherein the front cutting portion includes at least three planar surfaces (51;52;53).
7. Device according to one of the claims 1 to 6 wherein the cutting head (40) has at least five blades (41).
8. Device according to one of the claims 1 to 7 wherein the drive shaft (102) and reamer head (20) each has a cannulation (22;110), with the drive shaft cannulation (110) aligning with the reamer head cannulation (22) when the tubular shank (25) is engaged with the drive shaft (102) to form a center channel through the device.
9. Device of claim 8 further comprising an aspiration tube (13) for removing cut material generated by the reamer head (20), the aspiration tube (13) having a manifold assembly (12) at a proximal end, a reamer head retainer (14;14') at a distal end, and a lumen configured and dimensioned to receive the drive shaft (102).
10. Device of claim 9 wherein the center channel is in fluid communication with an irrigation source to provide irrigation to the cutting head (40) to assist in the removal of the cut material.
11. Device of claim 10 wherein:
- A) the manifold assembly (12) includes an irrigation port (15) connectable to the irrigation source and an irrigation chamber (35) in fluid communication with the irrigation port (15); and
 - B) the drive shaft (102) has an opening (126) extending from an outer surface of the drive shaft (102) to the drive shaft cannulation (110) and located within the irrigation chamber (35).
12. Device of claim 11 wherein the drive shaft opening (126) has curved walls (128) to draw irrigation into the center channel from the irrigation chamber (35) as the drive shaft (102) rotates.
13. Device according to one of the claims 9 to 12 wherein the lumen of the aspiration tube (13) is in fluid communication with the plurality of flutes at the distal end and is in

fluid communication with a suction source at the proximal end.

14. Device of claim 13 wherein the manifold assembly (12) includes an aspiration port (16) connectable to the suction source.

15. Device according to one of the claims 9 to 14 wherein the reamer head retainer (14') has a substantially spherical outer profile.

16. A method for removing material from a medullary canal of a bone comprising the steps of:

- A) reaming an area of the medullary canal to remove the material;
- B) irrigating the material to be removed while reaming to reduce generation of heat and move removed material from the reaming area; and
- C) aspirating the removed material while reaming to create a negative intramedullary canal pressure to assist in the removal of the material.

17. Method of claim 16 further comprising the step of inserting an implant in the medullary canal after the removal of material.

18. Method of claim 16 or 17 wherein the reaming is done with a single reaming device to reduce reaming time.

19. Method according to one of the claims 16 to 18 which further comprises guiding the reaming device into the medullary canal using a guide wire which passes through a cannulation in the reaming device.

20. Method according to one of the claims 16 to 19 further comprising the step of harvesting the removed material for future use.

FIG 1A

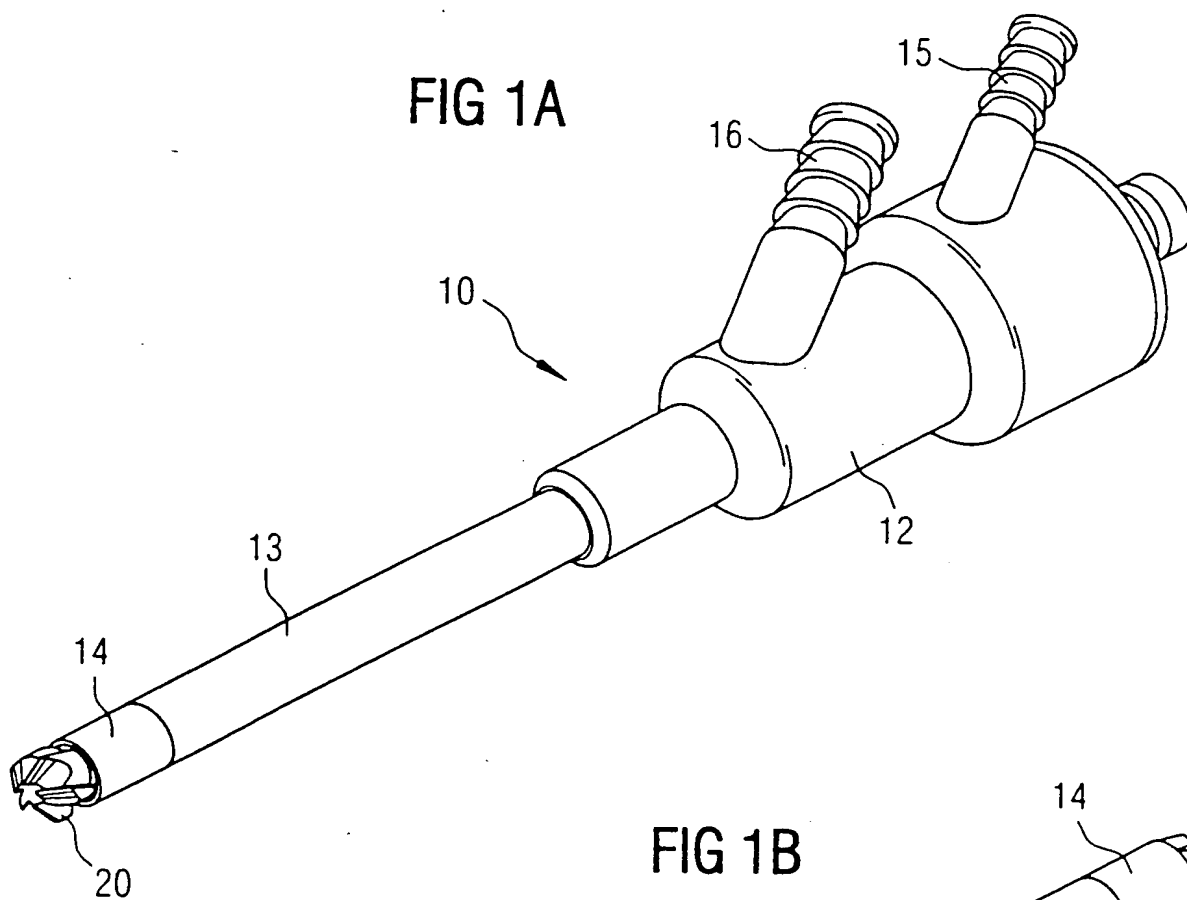
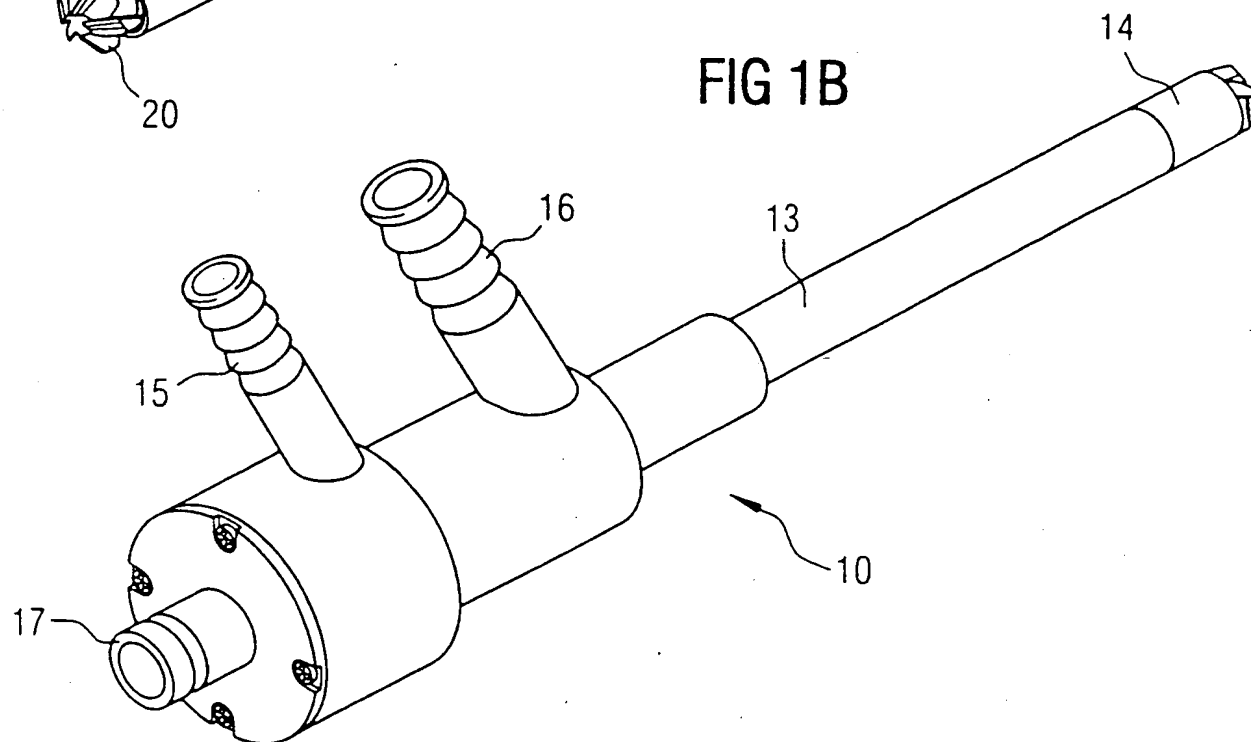
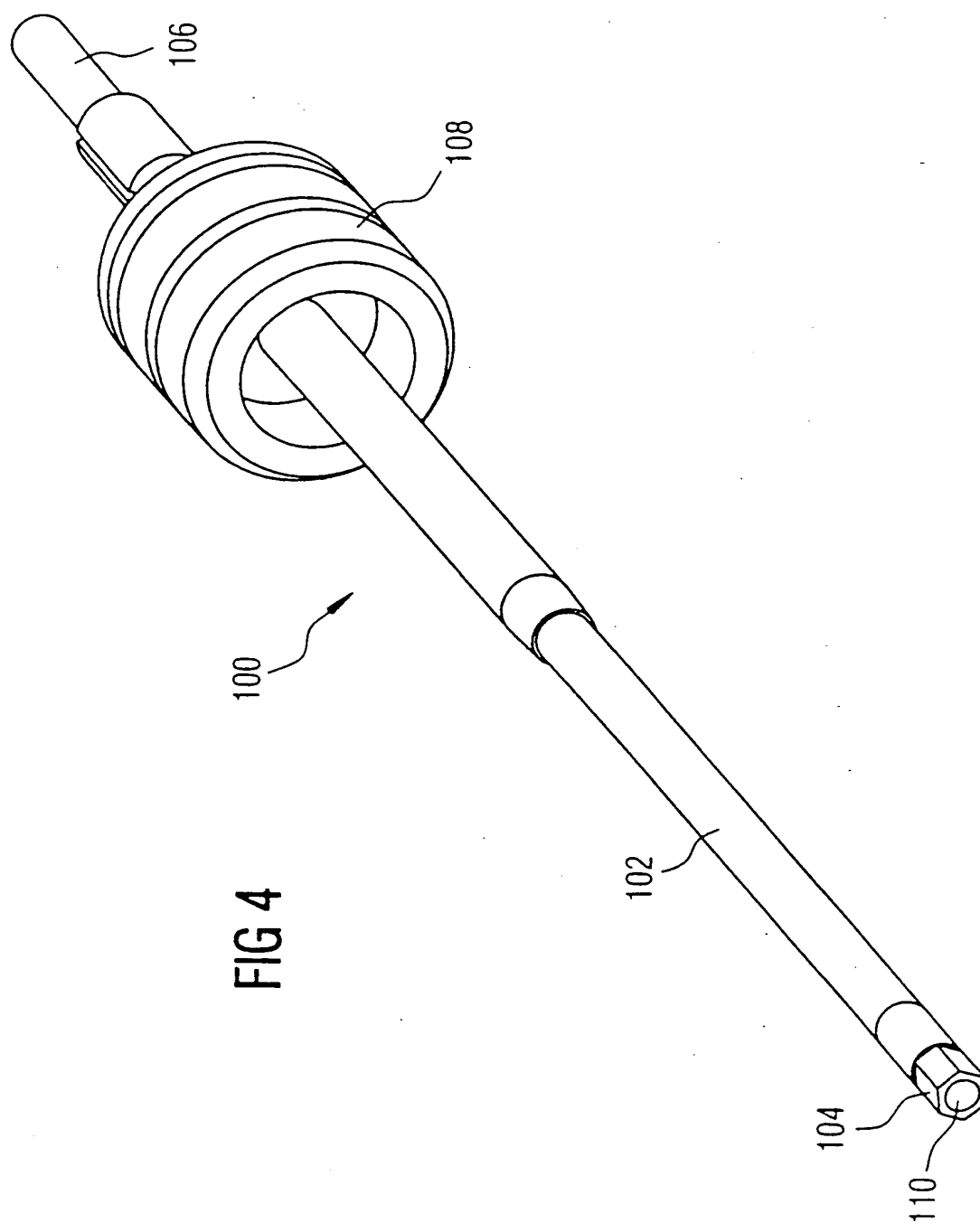


FIG 1B





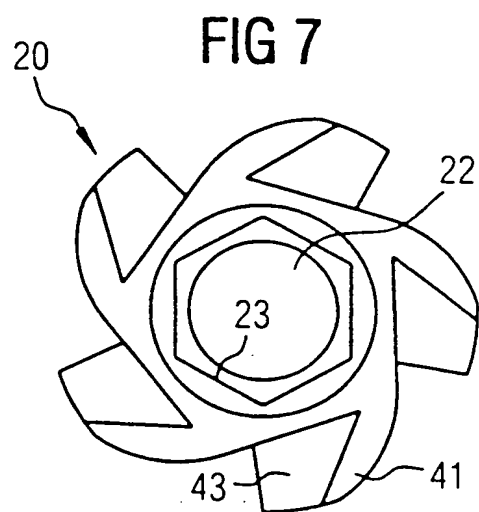
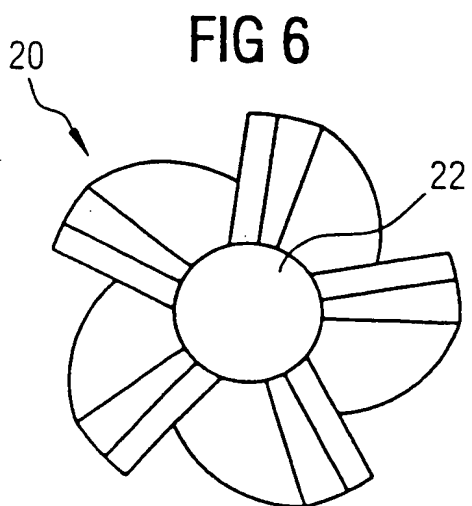
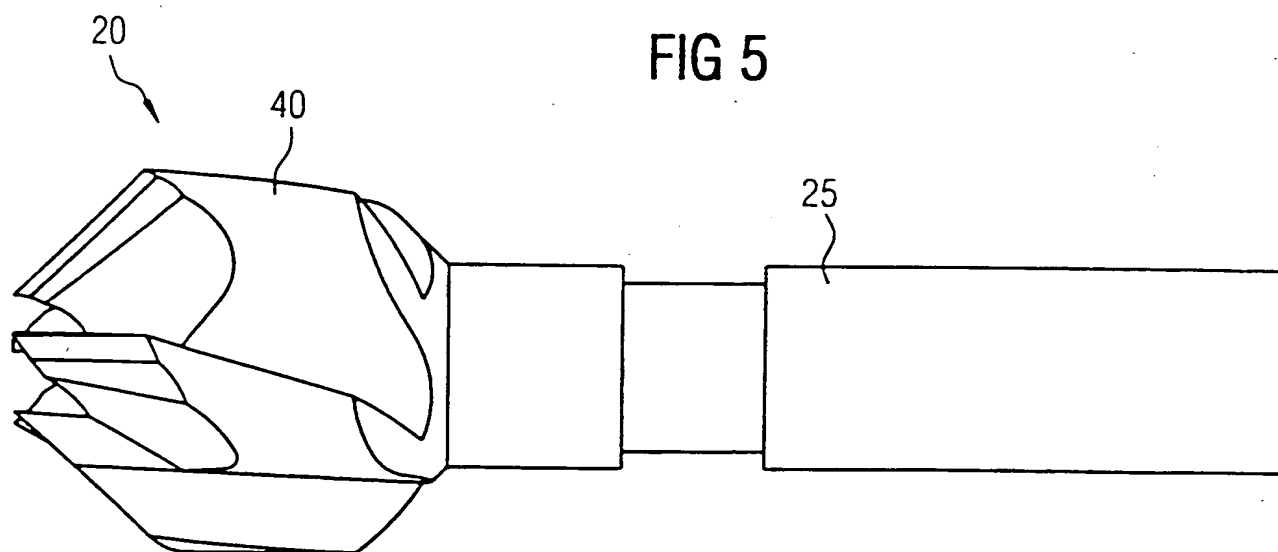


FIG 8

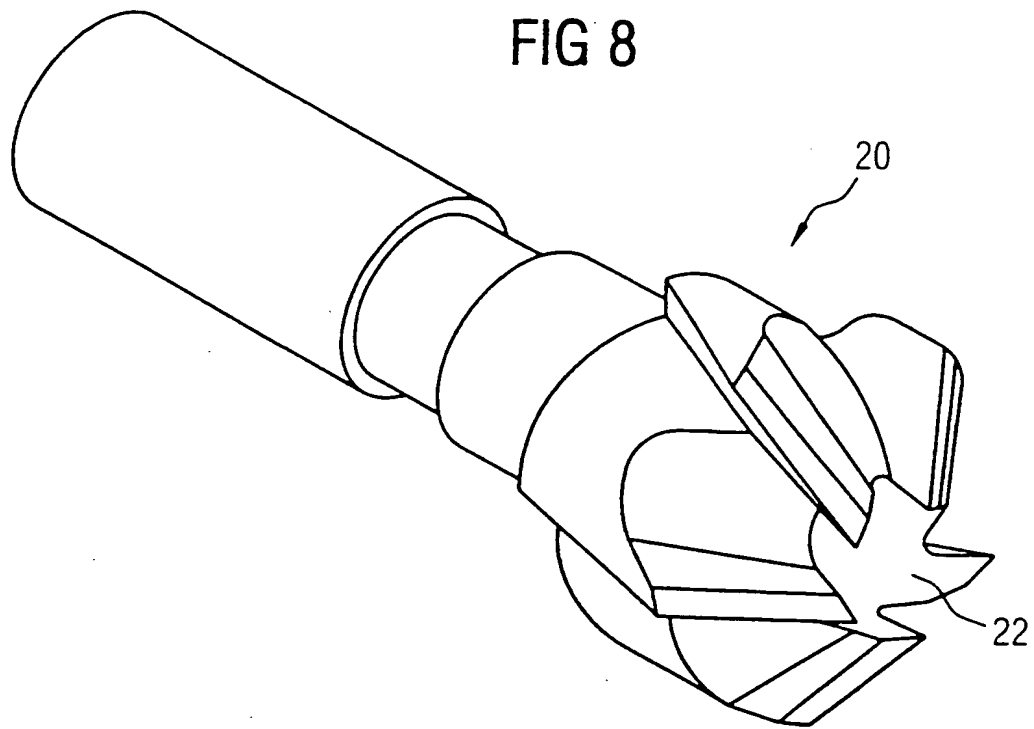


FIG 9

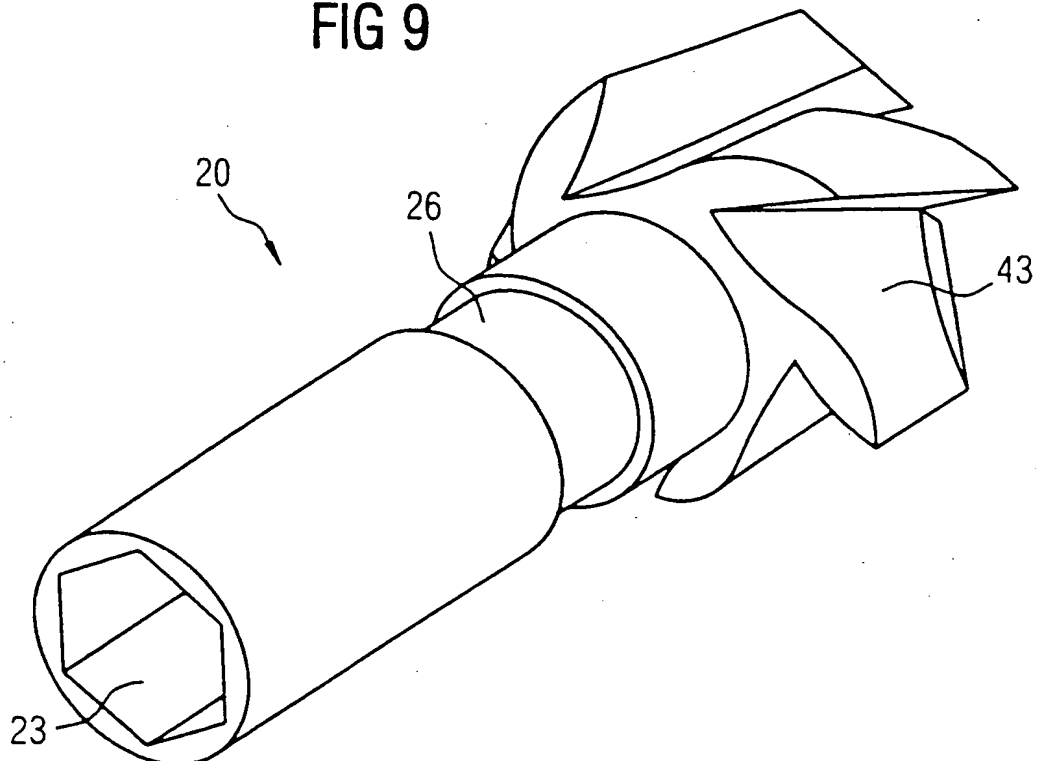
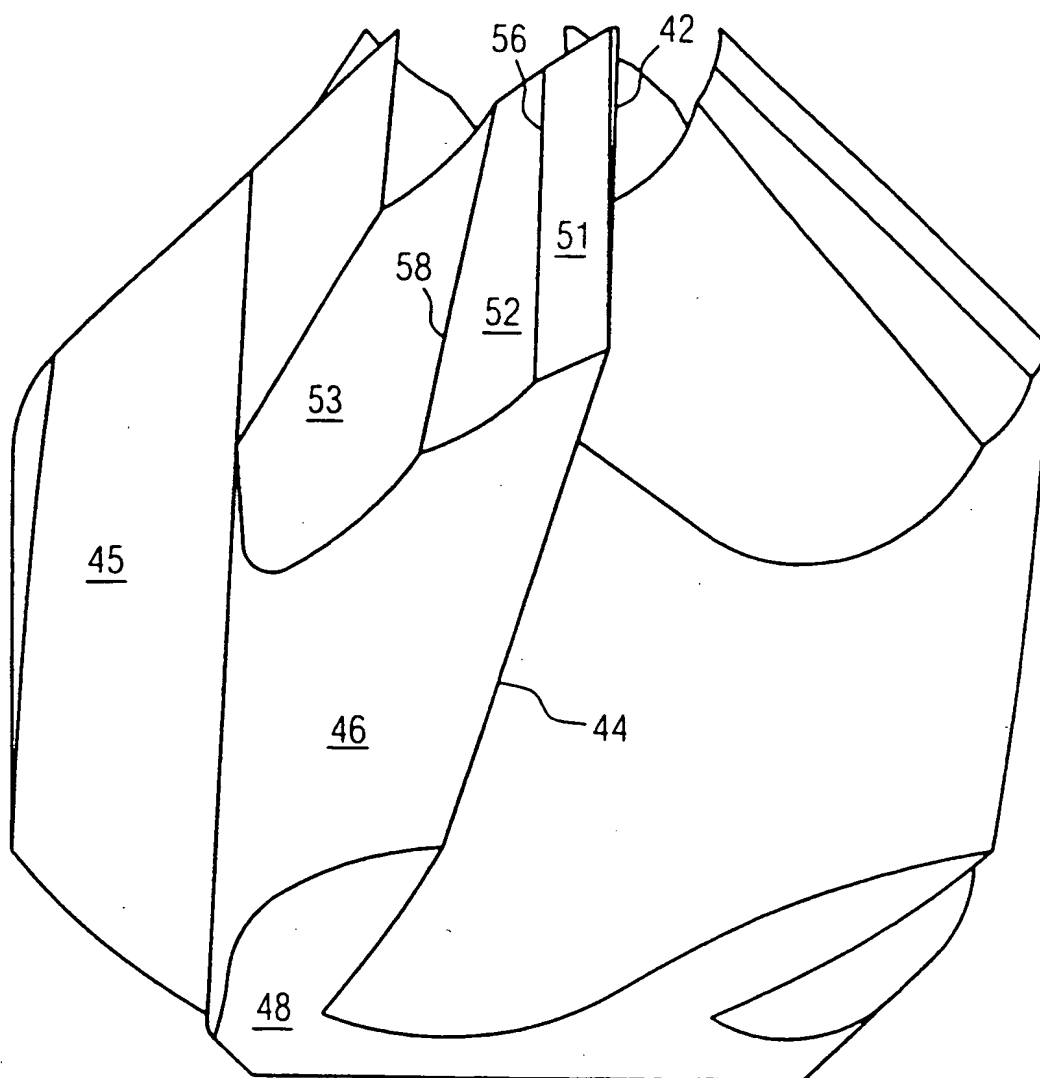
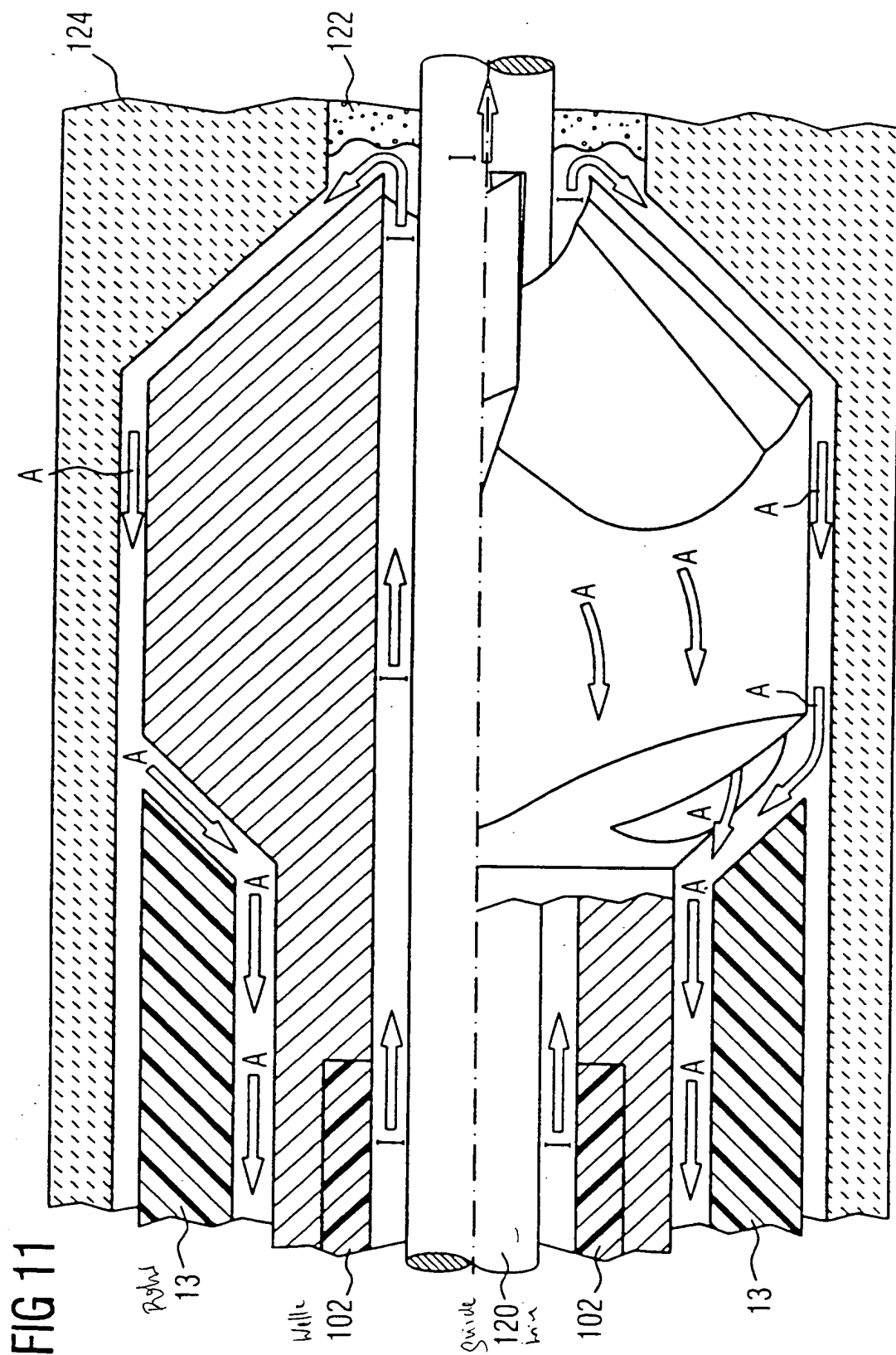


FIG 10





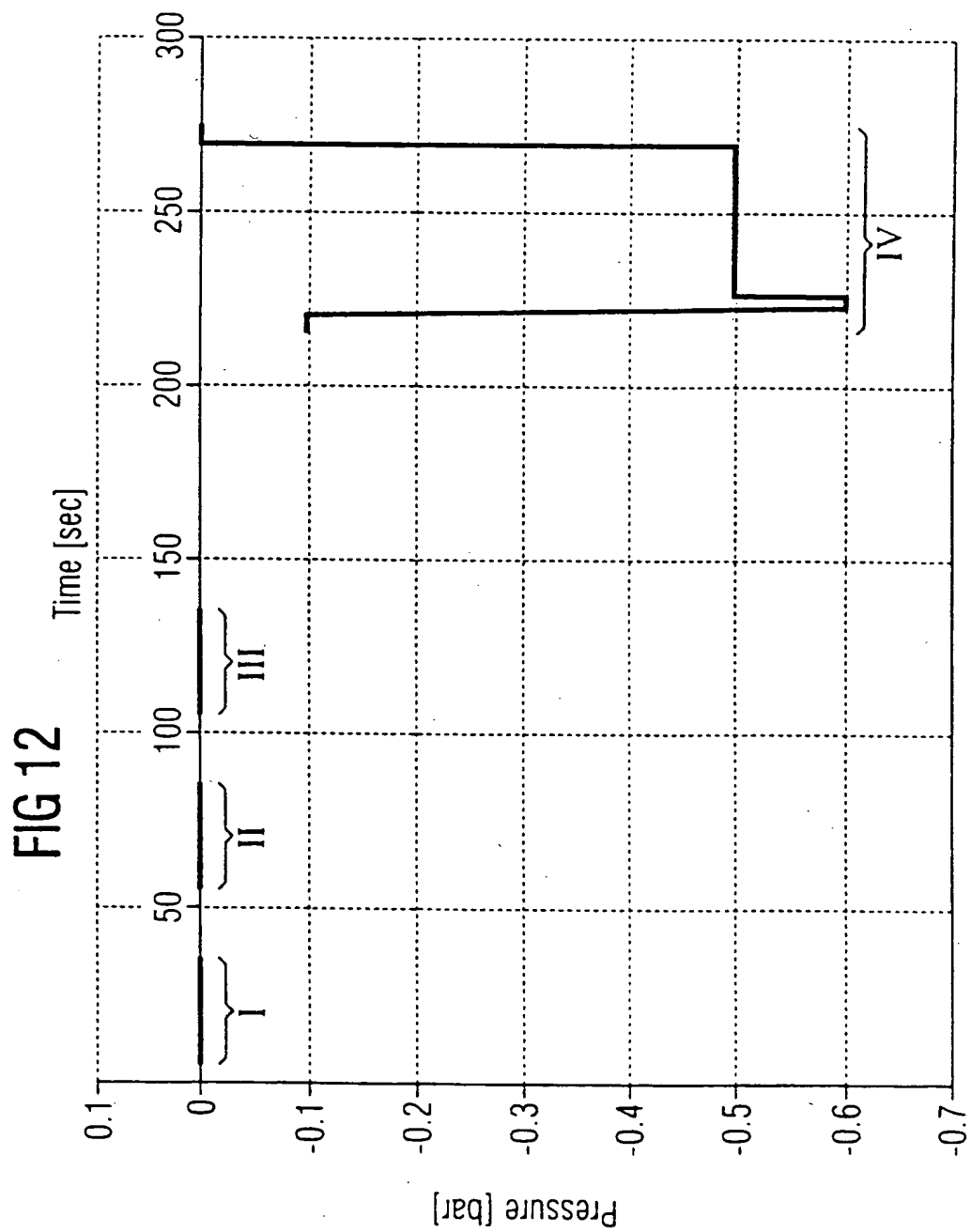


FIG 13

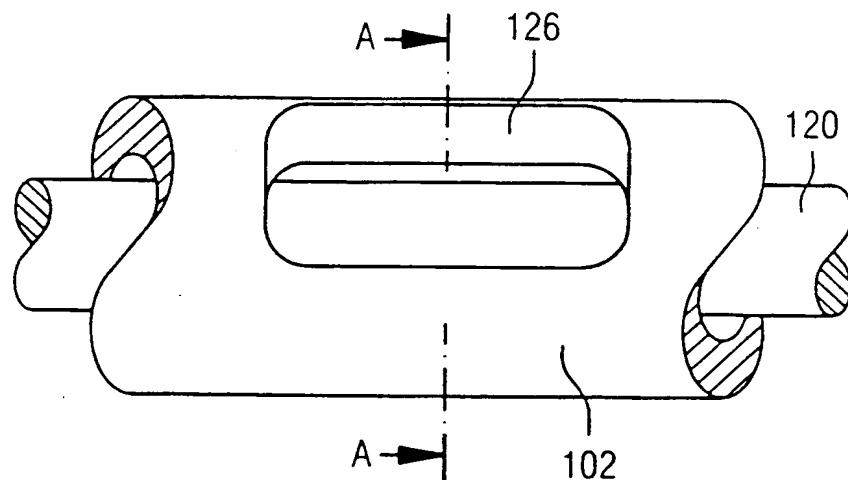
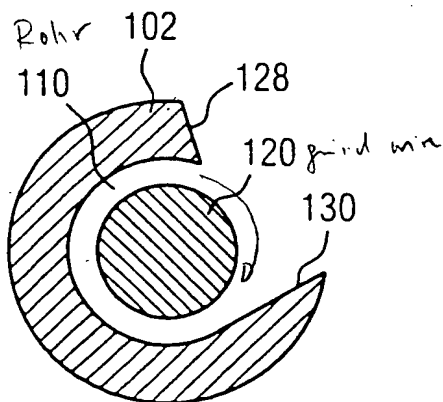


FIG 14



10 / 12

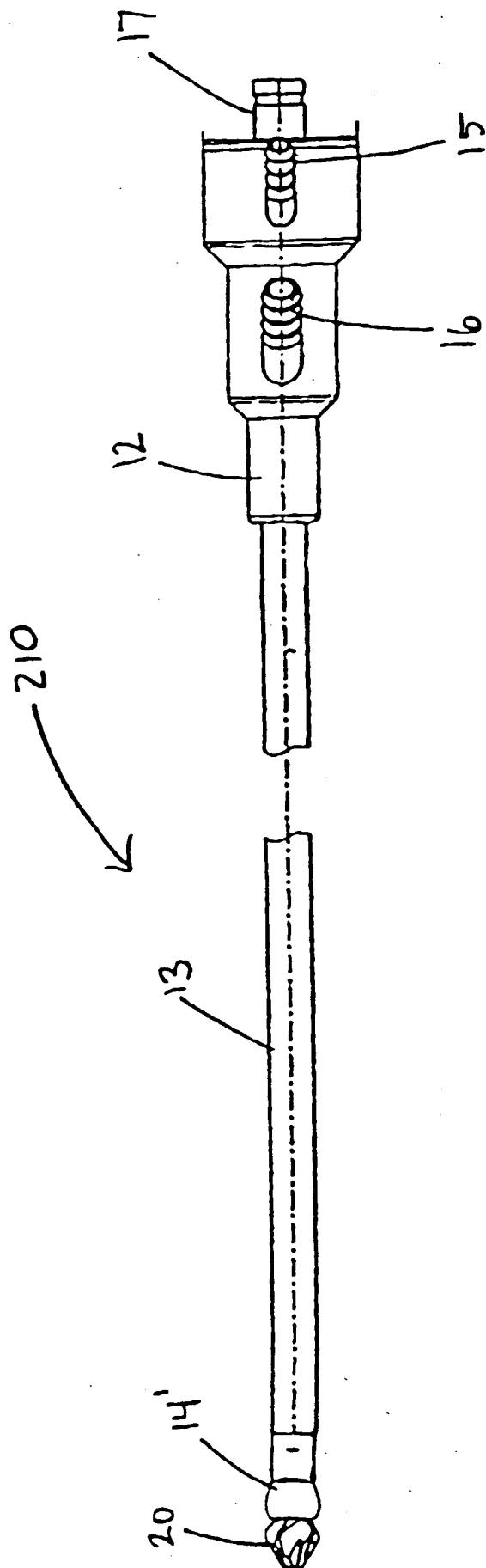


Fig. 15

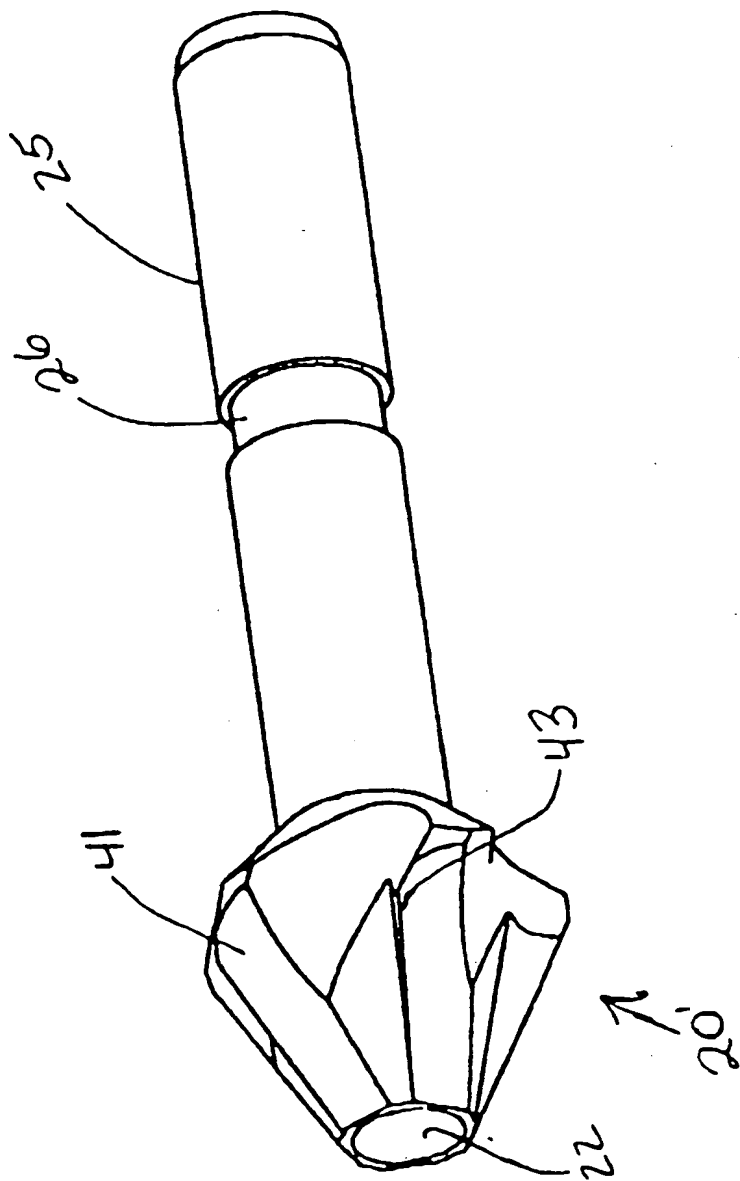


FIG. 16

12 / 12

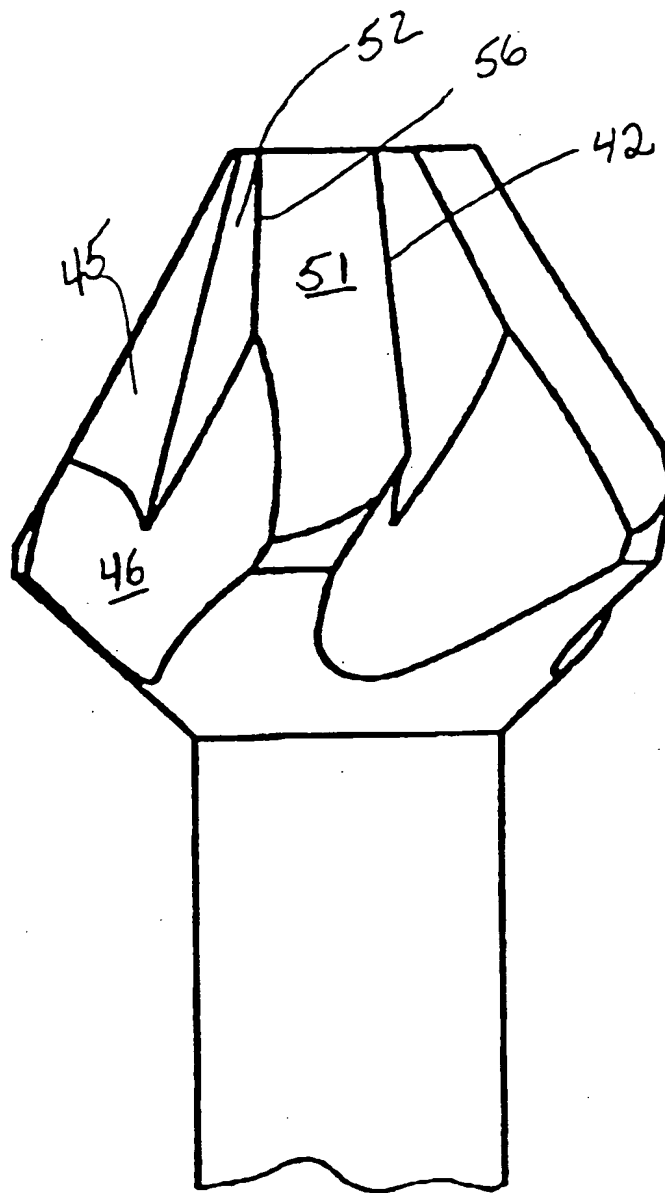


FIG 17

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CH 00/00051

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 197 19 051 A (D.PENNIG AND T.GAUSEPOHL)	1,6
Y	12 November 1998 (1998-11-12) figure 3	2-5, 7-11,13, 14
X	US 5 190 548 A (R.DAVIS) 2 March 1993 (1993-03-02) cited in the application figure 4	1
Y	US 5 720 749 A (G.A.RUPP) 24 February 1998 (1998-02-24) column 5, line 47 - line 54; figures 11,19 -/-	2-5,7,8



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *A* document member of the same patent family

Date of the actual completion of the international search

17 April 2000

Date of mailing of the international search report

26/04/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Nice, P

INTERNATIONAL SEARCH REPORT

International Application No

PCT/CH 00/00051

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 269 785 A (P.M.BONUTTI) 14 December 1993 (1993-12-14) cited in the application column 5, line 36 - line 43 column 5, line 50 - column 6, line 14 column 10, line 23 - line 31; figures 1,3-5	9-11,13, 14
A	EP 0 836 833 A (BRISTOL-MYERS SQUIBB) 22 April 1998 (1998-04-22) column 7, line 41 - line 42; figure 7	15

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CH 00/00051

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 19719051 A	12-11-1998	AU 7529398 A WO 9849948 A	27-11-1998 12-11-1998
US 5190548 A	02-03-1993	AT 149317 T AU 641889 B AU 1134292 A CA 2061833 A DE 69217689 D DE 69217689 T EP 0508710 A JP 5103790 A	15-03-1997 30-09-1993 15-10-1992 11-10-1992 10-04-1997 03-07-1997 14-10-1992 27-04-1993
US 5720749 A	24-02-1998	NONE	
US 5269785 A	14-12-1993	US 5403317 A US 5577517 A US 5694951 A US 5935131 A	04-04-1995 26-11-1996 09-12-1997 10-08-1999
EP 0836833 A	22-04-1998	US 5851208 A CA 2217469 A	22-12-1998 15-04-1998

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CH 00/00051

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 16-20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-8
Reamer with blades having a front cutting portion and a helical side cutting portion
2. Claims: 9-14
Reamer with aspiration/irrigation
3. Claims: 15
Reamer with spherical reamer head retainer